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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,926

12/16/2005

Lone Andersen

05198-P0008A

6586

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7590

02/17/2010

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EXAMINER

DEES, NIKKI H

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

02/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,926	Applicant(s) ANDERSEN ET AL.	
	Examiner Nikki H. Dees	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,10-13 and 15-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,10-13 and 15-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on October 21, 2009, has been entered. Claims 1, 2, 4-6, 8, 10-13 and 15-66 are currently pending in the Application. The previous 112 rejection of claim 6 has been withdrawn in view of the amendment to claim 6. The previous 112 rejection of claim 26 has been withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4-6, 8, 10-13, 15-17, 20-43, 46, 51-53, and 63-66 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Bunczek et al. (6,013,287).

4. Regarding claims 1, 2, 5, 8, 12, 16, 22, 23-27 and 63-66, Bunczek et al. disclose a chewing gum comprising at least one polyester polymer, wherein at least one of said polyester polymers is produced through the reaction of an alcohol or derivative thereof and an acid or derivative thereof. The teaching "at least one" is considered to meet Applicant's claims to two biodegradable polymers as "at least one" clearly indicates that there could be more than one of the polymers present. The chewing gum also comprises a polyester polymer functioning as an elastomer plasticizer (col. 9 lines 41-

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44). Stated advantages of the invention are a gum base that is biodegradable, and that traditional elastomers and elastomer plasticizers are replaced with other polymers, indicating that the chewing gum of the invention may be substantially or totally free of non-biodegradable polymers (col. 2 lines 61-64).

5. Regarding claim 2, the polymers may be hydrophilic, depending on the amount of fatty acids/alcohols utilized in the invention (col. 3 lines 10-64). A less hydrophobic polyester is understood to be more hydrophilic.

6. Regarding claims 22-27, the polyester of Bunczek et al. may be used as elastomers and/or elastomer plasticizers in a gum base, comprising up to 80% by weight of the gum base. Other chewing gum ingredients include softeners and fillers (col. 9 lines 54-55).

7. Regarding claims 28-34, Bunczek et al. teach the chewing gum comprising flavoring agents in an amount ranging from about 0.1 to 15% by weight, preferably about 0.2 to 5% by weight. A number of conventional chewing gum flavoring agents are taught (col. 11 lines 57-67).

8. Regarding claims 35-40, sweeteners are taught for use in the chewing gum in an amount ranging from about 5% to 95% by weight of the gum. High-intensity sweeteners may be used in an amount ranging from about 0.02 to 8% by weight. High intensity sweeteners taught include sucralose, aspartame and alitame (col. 11 lines 11-14; 26-31; 39-45).

9. Regarding claims 41-43, the chewing gum may comprise softener in an amount ranging from about 0.5 to 15% by weight. Softeners include lecithin (col. 11 lines 3-5).

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10. Regarding claims 51 and 52, the chewing gum base may comprise filler in an amount ranging from 4 to 35 weight % (col. 9 line 67). This would result in the filler in the range as claimed in the chewing gum.

11. Regarding claim 53, the chewing gum may comprise desired color (col. 10 line 67).

12. Bunczek et al. are silent as to the M_n of their different biodegradable polymers functioning as elastomers and elastomer plasticizers in their invention. They are also silent as to the T_g of the different polymers.

13. However, given that the polyester polymers as taught by Bunczek et al. are to be used in chewing gums in place of conventional elastomers, elastomer plasticizers, and resins, the same functions as claimed by Applicants, it would have been considered obvious to utilize polymers having molecular weights (M_n) and T_g s in the ranges as claimed, absent any convincing arguments or evidence to the contrary. The M_n and T_g of the polymers used in chewing gums are known to affect the textural/chewing properties of the gum. One of ordinary skill would have been able to optimize the M_n and T_g of the polymers utilized in the chewing gum through no more than routine experimentation in order to achieve the desired chewing properties.

14. Claims 18, 19, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Grijpma et al. (5,672,367).

15. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

16. Bunczek et al. are silent as to their chewing gum comprising polyester polymers wherein the polymer is obtained by the polymerization of cyclic esters.

17. Regarding claims 18, 19, and 47-50, Grijpma et al. teach biodegradable polyester polymers for use in chewing gums produced from lactones in combination with cyclic esters as claimed by Applicants. Specific monomers taught to be polymerized include ϵ -caprolactone and trimethylene carbonate (col. 1 lines 50-55).

18. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum substantially free from non-biodegradable polymers would have found it obvious to combine the polymers of Bunczek et al. with the polymers of Grijpma et al. in order to provide a chewing gum having desirable chewing properties while at the same time being substantially biodegradable. As all of the polymers of the instant claims are known in the prior art for inclusion in chewing gums, one of ordinary skill would have been able to combine them into one chewing gum base in order to employ different properties of the polymers to provide a chewing gum product having the most favorable chewing and degradation properties. In the absence of unexpected results, this combination of known polymers is considered to be no different than the combination of non-biodegradable polymers for inclusion in chewing gums.

19. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Li et al. (6,153,231).

20. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

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21. Bunczek et al. are silent as to their chewing gum comprising active agents.

22. Li et al. teach pharmaceutical agents to be added to chewing gums comprising biodegradable polymers (col. 7, lines 60-61).

23. One of ordinary skill in the art at the time the invention was made wishing to incorporate active (pharmaceutical) agents into the chewing gum of Bunczek et al. would have found it obvious to include pharmaceutical agents as taught by Li et al. as it was known in the art to include active ingredients in chewing gum preparations. Undue experimentation would not have been required, and there would have been a reasonable expectation that the chewing gum of Bunczek et al. would have been a suitable delivery medium for the desired active ingredients.

24. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (6,013,287) in view of Meyers (5,433,960)

25. Bunczek et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

26. Bunczek et al. are silent as to their chewing gum being coated.

27. Meyers teaches coated chewing gum, wherein the coating comprises polyols, film forming agents, and additives as claimed (col. 3 lines 46-53). The coating may also comprise sugar-free coating agents (col. 10 lines 49-54).

28. One of ordinary skill in the art at the time the invention was made would have found it obvious to coat the chewing gum of Bunczek et al. with a coating as taught by Meyers in order to provide storage stability to the chewing gum since it is well known to

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coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective. Additionally, coating the chewing gum of Bunczek et al. would not have required undue experimentation as one of ordinary skill would have been familiar with the coating of chewing gum products as claimed.

29. Claims 1, 2, 4-6, 8, 10-13, 15-17, 20-43, 46, 51-53, and 63-66 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Cook et al. (6,441,126).

30. Regarding claims 1, 2, 5, 8, 12, 16, 22, 23-27 and 63-66, Cook et al. disclose a chewing gum comprising at least one polyester polymer. The teaching "at least one" is considered to meet Applicant's claims to two biodegradable polymers as "at least one" clearly indicates that there could be more than one of the polymers present. The polyester polymers may function as elastomers and/or elastomer plasticizer (Abstract; col. 7 lines 56-60). The polyester of Cook et al. may be used as elastomers and/or elastomer plasticizers in a gum base, comprising up to 80% by weight of the gum base. Other chewing gum ingredients include softeners and fillers (col. 7 lines 60-65).

31. Regarding claims 28-34, Cook et al. teach the chewing gum comprising flavoring agents in an amount ranging from about 0.1 to 15% by weight. Any known flavoring agent may be utilized in the composition to provide the desired flavor (col. 10 lines 13-25).

32. Regarding claims 35-40, sweeteners are taught for use in the chewing gum in an amount ranging from about 5% to 95% by weight of the gum. High-intensity sweeteners

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may be used in an amount ranging from about 0.02 to 8% by weight. High intensity sweeteners taught include acesulfame and alitame (col. 9 lines 31-35; 47-65).

33. Regarding claims 41-43, the chewing gum may comprise softeners, including lecithin, in an amount ranging from about 0.5 to 15% by weight (col. 9 lines 23-25).

34. Regarding claims 51 and 52, the chewing gum base may comprise filler in an amount ranging from 4 to 35 weight % (col. 8 line 20). This would result in the filler in the range as claimed in the chewing gum.

35. Regarding claim 53, the chewing gum may comprise the desired color (col. 9 lines 16-22).

36. Cook et al. are silent as to the Mn of their different biodegradable polymers functioning as elastomers and elastomer plasticizers in their invention. They are also silent as to the T_g of the different polymers.

37. However, given that the polyester polymers as taught by Cook et al. are to be used in chewing gums in place of conventional elastomers and elastomer plasticizers, the same function as claimed by Applicants, it would have been considered obvious to utilize polymers having molecular weights (Mn) and T_g s in the ranges as claimed, absent any convincing arguments or evidence to the contrary. The Mn and T_g of the polymers used in chewing gums are known to affect the textural/chewing properties of the gum. One of ordinary skill would have been able to optimize the Mn and T_g of the polymers utilized in the chewing gum through no more than routine experimentation in order to achieve the desired chewing properties.

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38. Claims 18, 19, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Grijpma et al. (5,672,367).

39. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

40. Cook et al. are silent as to their chewing gum comprising polyester polymers wherein the polymer is obtained by the polymerization of cyclic esters.

41. Regarding claims 18, 19, and 47-50, Grijpma et al. teach biodegradable polyester polymers for use in chewing gums produced from lactones in combination with cyclic esters as claimed by Applicants. Specific monomers taught to be polymerized include ϵ -caprolactone and trimethylene carbonate (col. 1 lines 50-55).

42. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum substantially free from non-biodegradable polymers would have found it obvious to combine the polymers of Cook et al. with the polymers of Grijpma et al. in order to provide a chewing gum having desirable chewing properties while at the same time being substantially biodegradable. As all of the polymers of the instant claims are known in the prior art for inclusion in chewing gums, one of ordinary skill would have been able to combine them into one chewing gum base in order to employ different properties of the polymers to provide a chewing gum product having the most favorable chewing and degradation properties. In the absence of unexpected results, this combination of known polymers is considered to be no different than the combination of non-biodegradable polymers for inclusion in chewing gums.

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43. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Li et al. (6,153,231).

44. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

45. Cook et al. are silent as to their chewing gum comprising active agents.

46. Li et al. teach pharmaceutical agents to be added to chewing gums comprising biodegradable polymers (col. 7, lines 60-61).

47. One of ordinary skill in the art at the time the invention was made wishing to incorporate active (pharmaceutical) agents into the chewing gum of Cook et al. would have found it obvious to include pharmaceutical agents as taught by Li et al. as it was known in the art to include active ingredients in chewing gum preparations. Undue experimentation would not have been required, and there would have been a reasonable expectation that the chewing gum of Cook et al. would have been a suitable delivery medium for the desired active ingredients.

48. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (6,441,126) in view of Meyers (5,433,960)

49. Cook et al. teach a chewing gum comprising at least one polyester polymer as detailed above.

50. Cook et al. are silent as to their chewing gum being coated.

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51. Meyers teaches coated chewing gum, wherein the coating comprises polyols, film forming agents, and additives as claimed (col. 3 lines 46-53). The coating may also comprise sugar-free coating agents (col. 10 lines 49-54).

52. One of ordinary skill in the art at the time the invention was made would have found it obvious to coat the chewing gum of Bunczek et al. with a coating as taught by Meyers in order to provide storage stability to the chewing gum since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective. Additionally, coating the chewing gum of Bunczek et al. would not have required undue experimentation as one of ordinary skill would have been familiar with the coating of chewing gum products as claimed.

Double Patenting

53. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6, 8, 10-13 and 15-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 13-18, 24-26, 28-39 and 40-54 of copending Application No. 11/088,109.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim chewing gum comprising at least two different biodegradable polymers. The different glass transition temperatures and molecular weights of the instant claims are considered to be obvious over the conflicting claims where the at least two different biodegradable polymers perform the different functions of elastomer and elastomer plasticizer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

54. Applicant's arguments filed October 21, 2009, have been fully considered but they are not persuasive.

55. Applicant argues (Remarks, p. 21) that the "specific and unexpected benefits" from the claimed combination of polymers are not disclosed or suggested by Bunczek et al.

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56. The Examiner notes that the "specific and unexpected benefits" to which Applicant refers are not part of the claim limitations. The claims are to a chewing gum composition comprising two different biodegradable polymers having T_g and molecular weights as claimed. Bunczek et al. is considered to meet these limitations for the reasons detailed in the rejection *supra*. Further, Bunczek et al. speak to their product providing "improved chewing gum formulations," (col. 3 lines 4-5) indicating that the products of their composition are also considered to provide benefit over the products of the prior art. Bunczek et al. also speak to an advantage of their invention in the form of a biodegradable gum base (col. 2 lines 60-61). Applicant has not presented convincing arguments or evidence that the polymers of Bunczek et al. do not possess the physical characteristics as required by the instant claims. One of ordinary skill in the chewing gum art at the time the invention was made would have been able, through no more than routine experimentation, to arrive at desirable chewing gum formulations providing "benefits" over compositions of the prior art based on the teachings of Bunczek et al.

57. Applicant notes that Bunczek teach the combination of a biodegradable polymer with a synthetic elastomer (Remarks, p. 23).

58. Bunczek et al. also clearly teach the desirability of replacing traditional elastomers and elastomer plasticizers with the polymers of their invention to provide a biodegradable gum base (col. 2 lines 60-64). While all examples of Bunczek et al. may not have replaced all synthetic elastomers and elastomer plasticizers with biodegradable elastomers and elastomer plasticizers, the idea of doing so in order to

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provide a biodegradable chewing gum was clearly put forth by Bunczek et al. and is not considered to be a new or unobvious contribution of the instant invention.

59. Regarding the above para. 18 (Remarks, p. 23), the combination of Bunczek et al. and Grijpma et al. is used to reject claims 18, 19, and 47-50. The combination teaches the polymers as required by the claims. As both Bunczek et al. and Grijpma et al. teach biodegradable polyester polymers for use in producing biodegradable chewing gums, the examiner maintains one of ordinary skill would have been able to combine the polymers to arrive at a biodegradable chewing gum having desirable chewing characteristics.

60. Applicant argues (Remarks, pp. 24-26) that Cook et al. fails to provide the necessary guidance to arrive at the claimed invention.

61. The examiner maintains that it would have been obvious to arrive at polymers having a Tg and molecular weight as claimed based on the teachings of Cook et al. as the polymers in the invention of Cook et al. are to be used in the same capacity (i.e. chewing gum base) as the polymers of the instant invention. Applicant has not presented convincing arguments or evidence that the polymers of Cook et al. do not possess the physical characteristics as required by the instant claims.

62. It is noted that the double-patenting rejection is not addressed in the Remarks other than to indicate a Terminal Disclaimer may be filed if deemed appropriate in the future.

Conclusion

63. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794